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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,097	02/07/2001	Hideki Yoshioka	202907US-2SRD DIV	7771
22850	7590 03/29/2004			
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER AHMED, SAMIR ANWAR	
			ART UNIT 2623	PAPER NUMBER

DATE MAILED: 03/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/778,097

Applicant(s)

YOSHIOKA ET AL.

Examiner

Samir A. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5, 7, 8</u> . | 6) <input type="checkbox"/> Other: ____.  |

1. The specification is replete with grammatical errors too numerous to mention specifically. The specification should be revised carefully. Examples of such errors are: "hear" in page 83, line 21.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "20" in Fig. 53 and "321" in Fig. 54. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40, recites "means for obtaining an amount of a cardiac wall movement by correlating the cardiac wall contour divisions of one of the heart images to those of another", on lines 7-8. There is no disclosure in the specification as originally filed of neither "means for obtaining an amount of a cardiac wall movement by correlating the

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cardiac wall contour divisions of one of the heart images to those of another” nor how to perform it. The specification as originally filed discloses associating division points having the same numbers for respective time phases with one another (see Fig. 56) and movement distances of the division points in respective time periods are calculated (see page 90, lines 6-12).

Claim 43, recites “determination means for determining from the heart images an image corresponding to a reference time; and means for obtaining an amount of movement from the cardiac wall contour divisions corresponding to the image corresponding to the reference time”, lines 7-10. There is no disclosure in the specification as originally filed of “determination means for determining from the heart images an image corresponding to a reference time; and means for obtaining an amount of movement from the cardiac wall contour divisions corresponding to the image corresponding to the reference time” nor how to perform it. The specification as originally filed discloses pre-setting a contour E1 in a certain time phase as a reference time phase with respect to the periodic diastole and systole movement of the heart (page 88, lines 8-20).

Claim 44, recites “an input section configured to input heart images generated in a time-series and speed information of heartbeats synchronizing with the heart images”, lines 2-3. There is no disclosure in the specification as originally filed of synchronizing speed information of heartbeats with neither the heart images nor how to perform it.

Claim 45, recites “an input section configured to input heart images generated in a time-series and speed information of heartbeats synchronizing with the heart images”,

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lines 2-3, and "a detection section configured to detect a dynamic range of the amount of movement for at least one of each cardiac wall contour division", lines 11-13. There is no disclosure in the specification as originally filed of synchronizing speed information of heartbeats with neither the heart images nor how to perform it. There is no disclosure in the specification as originally filed of "a detection section configured to detect a dynamic range of the amount of movement for at least one of each cardiac wall contour division" nor how to perform it. The specification as originally filed discloses in Fig. 69, step D8 detecting a dynamic range. However in step D7 reading the speed information, in step D9 allot display colors and in D 10, display velocity information with display colors, which simply means that the dynamic range determined in step D8 is for speed information that is displayed in step D 10.

Claim 45, recites "a detection section configured to detect a dynamic range of the amount of movement for at least one of each cardiac wall contour division", lines 11-13 and "an allocation section configured to allocate a display color, used for displaying, the speed information on a display screen, to the dynamic range", lines 14-15. There is no disclosure in the specification as originally filed of how to allocate a display color, used for displaying, the speed information on a display screen, to the dynamic range which is "a dynamic range of the amount of movement", as recited in lines 11-13 of the claim

As to claim 46 refer to claim 40 rejection.

As to claim 49 refer to claim 43 rejection.

As to claim 50 refer to claim 44 rejection.

As to claim 51 refer to claim 45 rejection.

As to claim 52 refer to claim 40 rejection.

As to claim 55 refer to claim 43 rejection.

As to claim 58 refer to claim 45 rejection.

***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "limitations listed above in paragraph 4" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 42-43, 45, 48-49, 51, 54-55, 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "display at least the adjacent contour divisions" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "division points of the cardiac wall contour divisions" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim.

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Claim 45 recites the limitation " each division point of the cardiac wall contour division" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim.

As to claim 48 refer to claim 42 rejection.

As to claim 49 refer to claim 43 rejection.

As to claim 51 refer to claim 45 rejection.

As to claim 54 refer to claim 42 rejection.

As to claim 55 refer to claim 43 rejection.

Claim 57 recites the limitation "classifying the speed information of heartbeats" in line 1. There is insufficient antecedent basis for this limitation in the claim.

As to claim 58 refer to claim 57 rejection.

The claims are replete with inconsistencies and 112, first and second paragraphs and will be rejected by the Examiner as best as being understood.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 40-41, 46-47, 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura, Takashi et al. (Japanese. Pat. Application. KOKAI Publication No. 4-270983).

As to claim 40, Nakamura discloses, a heart function analysis apparatus comprising:

an extraction section configured to extract a cardiac wall contour from each of a plurality of heart images generated in a time-series [left ventricle contours ED5 and ES5 of each tomography image is extracted in step 403, from a time series of images (figs. 7 and 8)] ;

a division section configured to divide the cardiac wall contour of each of the heart images' into a plurality of cardiac wall contour divisions, using a point having a structural feature of the heart as a reference [divides the contour of each cardiac image (step 405). It is clear from Fig. 5 that the contour is divided using as references the heart proximal portion 51 and the heart apical portion 53, which have the structural characteristics of the heart]; and

means for obtaining an amount of a cardiac wall movement by correlating the cardiac wall contour divisions of one of the heart images to those of another [the apparatus associates the divided contours with the different tomography images in the time series (corresponding to tomography images in an end period of ectasia and an end period of contraction), to detect the heart wall movement] .

As to claim 41, Nakamura further discloses, wherein the point having a structural feature corresponds to at least one of a cardiac apex, an annulus valva and a papillary muscle [cardiac Apex (Fig. 5, portion 53)].

As to claim 46 refer to claim 40 rejection.

As to claim 47 refer to claim 41 rejection.



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As to claim 52 refer to claim 40 rejection.

As to claim 53 refer to claim 41 rejection.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 42, 48, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura, Takashi et al. (Japanese. Pat. Application. KOKAI Publication No. 4-270983) as applied to claims 40, 46, 52 above and further in view of Sheehan al. (U. S. Patent 5,601,084).

As to claim 42, Nakamura further discloses color displaying the heart wall movement as shown in Fig. 6. Nakamura does not specifically disclose, wherein said means for obtaining a cardiac wall movement comprises:

means for classifying the cardiac wall contour divisions for plural positions of a cardiac wall to display at least the adjacent contour divisions with different colors or different luminance. However classifying cardiac functions such as heart wall motion by color coding (using different colors) is well known in the art as disclosed by Sheehan.

Sheehan discloses a method for imaging the heart and analyzing characteristic cardiac parameters of a patient's heart (col. 2, lines 62-65). The image of the heart is

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presented to the user in color so that parameters are readily evident based on a defined color-coding. For example, the color coding (using different colors) can represent regional cardiac functions, or abnormality regional functions, perhaps as expressed in units of standard deviations from the mean of a normal reference population. In this context, regional functions are intended to mean a cardiac wall motion (col. 13, lines 14-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Sheehan to modify Nakamura's apparatus by classifying the cardiac wall contour divisions for plural positions of a cardiac wall to display the wall contour divisions in different color in order to make cardiac parameters readily evident to the user based on their color coding.

As to claim 48 refer to claim 42 rejection.

As to claim 54 refer to claim 42 rejection.

12. Claims 43, 49, 54, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nakamura, Takashi et al. (Japanese. Pat. Application. KOKAI Publication No. 4-270983) and Zhu al. (U. S. Patent 6,236,738)

As to claim 43 refer to claim 40 rejection for their common features. Nakamura further discloses,

a display device configured to display the amount of movement with one of a numerical display, a graphical display and a color display of the cardiac wall [the apparatus has a structure for color-displaying the heart wall movement as shown in Fig. 6.] , and the different tomography images corresponding to tomography images in an

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end period of ectasia and an end period of contraction. Nakamura does not specifically disclose,

determination means for determining from the heart images an image corresponding to a reference time;

means for obtaining an amount of movement from the cardiac wall contour divisions corresponding to the image corresponding to the reference time or division points of the cardiac wall contour divisions, for each cardiac wall contour division or each division point.

Zhu discloses a method for non-rigid cyclic analysis of a series of images by fitting a spatiotemporal finite element mesh model to motion data samples of an extended region at all time frames (Abstract). As shown in Fig, 1 the mesh points are partitioning the myocardium into divisions. A set of points is selected at a reference state ( $t_0$ ). The corresponding spatiotemporal trajectories of these points specify the mesh configuration at subsequent time instants and define the moving and deforming domain of each element (division). The amount of movement of the point at any time is calculated (col.5, line 18-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Zhu to modify Nakamura's apparatus by determining from the heart images an image corresponding to a reference time and obtaining an amount of movement from the cardiac wall contour divisions corresponding to the image corresponding to the reference time or division points of the cardiac wall contour divisions, for each cardiac wall contour division or each division point in order to track the motion of the heart during contraction which has

a correlation with some diseases such as regional contractile abnormality using a model that achieves satisfactory results in the presence of noise.

As to claim 49 refer to claim 43 rejection.

As to claim 55 refer to claim 43 rejection.

As to claim 56 refer to claim 43 rejection.

13. Claims 44, 50, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nakamura, Takashi et al. (Japanese. Pat. Application. KOKAI Publication No. 4-270983) and Yamazaki, Nobuo (Japanese. Pat. Application. KOKAI Publication No. 4-270983).

As to claim 44, refer to claim 43 rejection for their common features. Nakamura does not specifically disclose,

an input section configured to input heart images generated in a time-series and speed information of heartbeats synchronizing with the heart images;

a classification section configured to classify the speed information of heartbeats for each of positions of the cardiac wall contour divisions;

means for obtaining a speed statistic for each position of the cardiac wall contour divisions; and

a display device configured to display the speed statistic with at least one of a numerical display, a graph display and a color display of a cardiac wall.

Yamazaki discloses a cardiac function analysis apparatus which inputs heart images and speed information of heartbeats synchronizing with the heart images (Figs 46, 47). Divides a contour of a heart wall obtained by extracting a heart wall contour

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from a heat image, classify the speed information of heartbeats for each of positions of the cardiac wall contour divisions (Figs. 48-49), obtains rate information of a heart area and rate statistics, and display the rate statistics as a color display of the heart wall (see paragraphs (0159) to (0179) and Fig. 61. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Yamazaki to modify Nakamura's apparatus by obtaining and classifying the speed information of heartbeats, obtaining a speed statistic for the cardiac wall divisions and display the speed static on a color display in order to make cardiac parameter information readily evident to the user based on their color coding and clearly show the myocardium abnormalities.

As to claim 50 refer to claim 44 rejection.

As to claim 57 refer to claim 44 rejection.

14. Claims 45, 51, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nakamura, Takashi et al. (Japanese. Pat. Application. KOKAI Publication No. 4-270983) and Yamazaki, Nobuo (Japanese. Pat. Application. KOKAI Publication No. 4-270983) and further in view of Sheehan al. (U. S. Patent 5,601,084).

As to claim 45 refer to claim 44 for their common features. Neither Nakamura nor Yamazaki discloses,

a detection section configured to detect a dynamic range of the amount of movement for at least one of each cardiac wall contour division and each division point of the cardiac wall contour division.

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Sheehan discloses a method for imaging the heart and analyzing characteristic cardiac parameters of a patient's heart (col. 2, lines 62-65). The image of the heart is presented to the user in color so that parameters are readily evident based on a defined color-coding. For example, the color coding (using different colors) can represent regional cardiac functions, or abnormality regional functions, perhaps as expressed in units of standard deviations from the mean of a normal reference population. In this context, regional functions is intended to mean a cardiac wall motion (col. 13, lines 14-22). The range of cardiac wall motion is determined and displayed (col. 2, lines 49-51 col. 3, lines 54-63, col. 13, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teachings of Sheehan to modify the combined apparatus of Nakamura and Yamazaki by determining and displaying the range of cardiac wall contour motion in order to track surfaces of the heart on the graphically displayed images to define data at an end systole and at end diastole of the cardiac cycle and by dynamically viewing the range of motion of the cardiac wall, a medical practitioner can monitor dynamic changes in cardiac function with respect to the range of motion of the cardiac wall.

As to claim 51 refer to claim 45 rejection.


As to claim 58 refer to claim 45 rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samir A. Ahmed whose telephone number is 703-305-9870. The examiner can normally be reached on Mon-Fri 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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SA

  
**SAMIR AHMED  
PRIMARY EXAMINER**